K022800

510(k) Summary of Safety and Effectiveness Information
VisiQuant™ Anti-Nuclear Antibody Test System
Revised September 20, 2002

NOV 25 2002

Hyperion, Inc.
14100 S.W. 136th Street
Miami, FL. 33186
Contact Person: Radha Goolabsingh at 305-238-3020 x202 or Victor Rana at 305-238-3020 x208, or by facsimile at 305-232-7375.

Trade or Proprietary Name: VisiQuant™ Anti-Nuclear Antibody Test System

Common or Usual Name: VisiQuant™ ANA Test System

Classification Name: Anti nuclear antibody immunological test system

Registration Number: *Manufacturer*

Hyperion, Inc. 1028110
14100 S.W. 136th Street
Miami, Florida 33186

The proposed VisiQuant™ ANA System is substantially equivalent to the VisiQuant™ ANA Test Kit using a specially equipped fluorescent microscope, previously cleared under Document Control No., K013213, on 6/04/2002. The proposed and the predicate device are both *in-vitro* diagnostic products, intended for the visual determination of anti-nuclear antibodies (ANA's) immunofluorescence pattern(s) and the semi-quantitative measurement of ANA's in human serum sample with a single dilution as an aid in the diagnosis of auto-immune and connective tissue diseases such as systemic lupus erythematosus (SLE) and Sjogren's Syndrome. There are no changes to the test kit and the VisiQuant Microscope supplied meets the minimum requirements specified for the test kit in K013213.

The proposed VisiQuant™ ANA Test System uses the same VisiQuant™ ANA Test Kit as was previously cleared. Hyperion is now proposing to supply the VisiQuant™ Microscope as an additional reader for use with the VisiQuant™ ANA Test Kit.

The reading of the samples remains the same except that the software will now generate the calibration curve and interpolate the titer. The prepared slide is placed onto the stage of the microscope. The microscope focuses on the images of each well and the CCD camera collects the images. The software captures and stores the images. The operator views the images to determine if the sample is positive and identifies the pattern. For the samples determined to be positive by the operator, the software calculates a fluorescence intensity unit (FIU) value. The proposed software will now generate a 4-parameter curve using the FIUs and ANA titers of Calibrators assayed in the same run, from which the VisiQuant titer of the test sample is interpolated. The proposed software now has the capability of generating calibration curve reports and laboratory reports.

Method Comparison:

A comparative evaluation of the proposed VisiQuant™ ANA Test System demonstrated substantial equivalence to the VisiQuant™ ANA Test Kit using the specially equipped fluorescent microscope. The results are shown in the following tables and diagrams:

Table 2. Agreement in Test Results:

VisiQuant™ ANA Test Kit	No. of samples with VisiQuant™ ANA Test System		
	Negative	Positive	Total
Negative	40	2	42
Positive	0	71	71
Total	40	73	113

Agreement for negative results = 40/42 = 95.2%
Agreement for positive results = 71/71 = 100%

Table3. Qualitative Results: The following table shows the pattern agreement for the 71 samples found to be positive by both the VisiQuant™ ANA Test Kit and the VisiQuant™ ANA Test System.

Negative (**Neg**); Homogenous (**H**); Speckled (**S**); Nucleolar (**N**); Centromere (**C**)

VisiQuant™ ANA Test Kit	No. of samples with VisiQuant™ ANA Test System						
	H	S	N	C	H,S	H,N	Total
H	**31**						31
S		**19**			1		20
N			**1**				1
C				**2**			2
H,S	1				**6**		7
H,N						**10**	10
Total	32	19	1	2	7	10	71

Pattern agreement for samples positive by both tests = 69/71 = 97.2 %;

Table 4. Discrepant samples: Negative (Neg.), Not applicable (n.a); Speckled (S); Homogenous (H). Slight differences in reading could account for these discrepancies.

Sample ID	VisiQuant™ ANA Test Kit		VisiQuant™ ANA Test System	
	Titer	Pattern	Titer	Pattern
Y-SLE17	406	S	314	H,S
X-E4	713	H,S	526	H
Y-SS2	Neg.	n.a.	130	H
W-14	Neg.	n.a.	97	H,S

Seventy-one (71) serum samples, positive by both the proposed VisiQuant™ ANA Test System and the VisiQuant™ ANA Test Kit using the specially equipped fluorescent microscope were compared for ANA titers. The following figure shows the correlation with all patterns (Homogenous, Speckled, Nucleolar, Centromere and mixed).

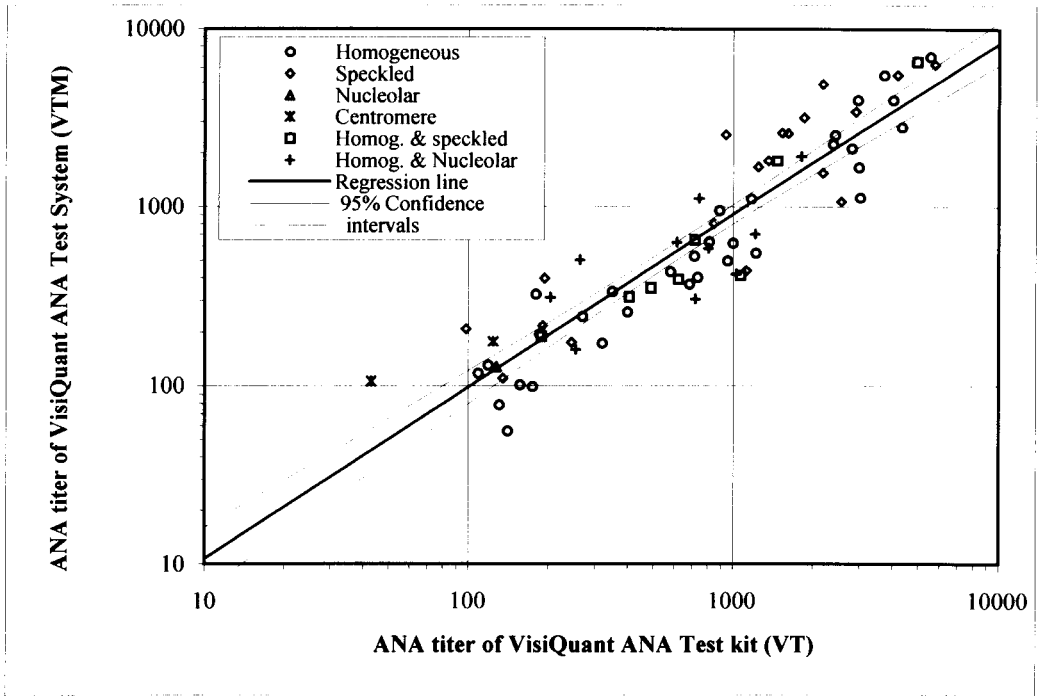

Fig. 1. Scatter diagram showing correlation in ANA titers for 71 positive results between VisiQuant™ ANA Test System and the VisiQuant™ ANA Test Kit using the specially equipped fluorescent microscope, with a correlation coefficient of 0.917 and a regression equation of Log VTM = 0.0578 + 0.966 Log VT. The Linear Regression and its 95% confidence intervals are also shown.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 5 2002

Ms. Radha Goolabsingh
Director of Quality Assurance and Regulatory Affairs
Hyperion, Inc.
14100 S.W. 136th Street
Miami, FL 33186

Re: k022800
Trade/Device Name: VisiQuant™ Anti-Nuclear Antibody Test System
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: Class II
Product Code: DHN
Dated: October 30, 2002
Received: October 31, 2002

Dear Ms. Goolabsingh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) NUMBER (IF KNOWN): K022800

DEVICE NAME: **VisiQuant™ Anti-Nuclear Antibody Test System**

INDICATIONS FOR USE: The VisiQuant™ Anti-Nuclear Antibody Test System is intended for the visual determination of anti-nuclear antibodies (ANA's) immunofluorescence pattern(s) and the semi-quantitative measurement of ANA's in human serum with a single dilution as an aid in the in-vitro diagnosis of auto-immune and connective tissue diseases such as systemic lupus erythematosus (SLE) and Sjogren Syndrome.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence Of CDRH, Office Of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ____

(Optional Format 1-2-96)

J P Reeves for J. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022800